

**REMARKS**

In the Office Action, Claims 1-10 were rejected. Claims 1 and 7-10 have been amended and Claims 2-4 have been canceled without prejudice herein. Claims 1 and 5-10 are now pending.

The Specification has been amended to correct a typographical error related to the term “amorphous” at page 1, line 20.

The Abstract has been amended to correct the chemical name of adefovir dipivoxil and, as suggested by the Examiner, to recite the steps of a method disclosed in the application. Support for these amendments can be found in the Specification at page 1, lines 13-15, and page 4, line 29, to page 5, line 2.

Claim 1 has been amended to recite the X-ray powder diffraction peaks in combination, rather than in the alternative. That is, the term “and/or” in the list of peaks was previously removed in the Preliminary Amendment filed on April 19, 2007, and the phrase “optionally one or more characteristic peaks” has been removed by the amendment herein. Also, Claim 1 has been amended by importing all the measured parameters recited in dependent Claims 2-4. As a result of this amendment, Claims 2-4 have been canceled without prejudice. Additional support for this amendment can be found in the specification at page 3, lines 12-32.

Claim 7 has been amended to recite proper antecedency regarding the term “unit dosage.” A similar was made to Claim 6 in the previous Preliminary Amendment.

Claims 8-10 have been amended for clarity and not for reasons related to patentability. In particular, the abbreviation “AD” has been spelled out. Also, the misspelling of “acetonitrile” has been corrected in Claim 9.

No new matter has been added by these amendments.

**Rejections Under 35 U.S.C. § 102**

The Office Action first rejected Claims 1 and 4-7 under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 99/04774, which is described in the present application. Specifically, the Office Action asserted that Form 1 in WO 99/04774 has a peak at about 17.2, which overlaps the peak at “about 17.24” recited in Claim 1. Given the original claim recited the list of peaks in the alternative, this single peak of WO 99/04774 was alleged to anticipate Claim 1. Applicant

respectfully traverses this rejection to the extent that it applies to the claims as amended herewith.

Claim 1 was previously amended in the Preliminary Amendment of April 19, 2007, to remove the term “and/or” between the listing of peaks. In the amendment herein, Claim 1 has been amended to remove the recitation of “optionally one or more characteristic peaks.” As such, amended Claim 1 recites a crystal that has the characteristic peaks expressed in terms of 2 $\theta$  at about 3.60, about 7.28, about 15.08, about 17.24, about 17.96, about 20.12, and about 22.24 in X-ray powder diffraction pattern with Cu target radiation. That is to say, the claimed crystal has 7 characteristic peaks, and one peak in common does not mean that the Form 1 in WO 99/04774 is the same crystal as the claimed crystal. In addition, the measured parameters of dependent Claims 2-4 have also been incorporated into Claim 1. Thus, because WO 99/04774 does not disclose the same crystal as that recited in amended Claim 1, this claim and those dependent therefrom are novel over this reference.

The Office Action next rejected Claims 1-7 under 35 U.S.C. § 102(a) as allegedly being anticipated by CN1396170. The Office Action indicated, however, that upon gaining the benefit of a priority date of November 12, 2002, this rejection will be withdrawn.

Upon national phase entry on May 11, 2005, and in accordance with 35 U.S.C. § 119(b) and 37 C.F.R. § 1.55(ii), the specification of the present application was amended to incorporate a priority claim to Chinese Patent Application 02148923.3 filed November 12, 2002. A copy of this Chinese Patent Application (the priority document) was also communicated to the US/RO. Applicants also submitted a certified copy of the priority document as well as a certified English translation thereof on February 27, 2008. Accordingly, Applicants are entitled to a priority date of November 12, 2002, under 35 U.S.C. § 119, and the rejection over CN139170 should be withdrawn.

The Office Action also rejected Claims 1-7 under 35 U.S.C. § 102(b)/103(c) as allegedly being anticipated by or, in the alternative, obvious over WO 00/35460. In particular, the Office Action asserted that the crystallization process given on page 30 of this reference shows the same compound recited in the present claims. While the reference is in fact silent on the particular crystallographic form present, the Office Action concluded that the present claims simply seek to

claim this known compound by reciting an unknown property thereof. As such, the Office Action required that Applicant provide evidence to distinguish the compound described in WO 00/35460 and the claimed crystal.

WO 00/35460, which is described in the present application, discloses formulations comprising AD and an excipient with or without L-carnitine-L-tartrate. The reference discloses a crystallization process at page 30 and Example 10 obtains 2.4 kg anhydrous crystal of AD. At page 4, lines 32-34, and page 5, lines 2-4, this reference mentions two crystals having endothermic transitions measured by DSC at about 102°C and 73°C, respectively. Certainly, the two crystals must be produced by the process described in the reference. Amended Claim 1 recites a crystal that has an endothermic peak at about 94.5°C in DSC thermogram, which distinguishes the claimed crystal from the crystals mentioned in WO 00/35460. Thus, the amended Claim 1, at least for this reason, is novel over WO 00/35460.

#### **Rejections Under 35 U.S.C. § 112**

The Office Action rejected Claims 1-10 under 35 U.S.C. § 112, 2¶, as allegedly failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Specifically, the Office Action alleged that the abbreviation “AD” was unclear and should be defined. While the claims are clear as written and the skilled artisan would easily understand what the abbreviation “AD” referenced, especially since this abbreviation is expressly defined at page 1, line 13, of the specification, Applicants have amended the claims to replace the abbreviation “AD” with the term “adefovir dipivoxil.”

The Office Action also noted that the recitation of “step b” and “step c” in Claim 9 do not have antecedent basis in base Claim 8. In the Preliminary Amendment filed April 19, 2007, the bulleted steps of Claim 8 were corrected to read steps a through d. Thus, the reference to “step b” and “step c” in Claim 9 has proper antecedent basis.

In light of the amended claims, the rejections under 35 U.S.C. § 112, 2¶, are believed to be overcome.

The Office Action rejected Claims 1-10 under 35 U.S.C. § 112, 1¶, as allegedly failing to comply with the enablement requirement. In particular, the Office Action asserted that by use of the terms “and/or” between the list of peaks, the claims are drawn to just a single peak. The term

“and/or” was removed in the previous Preliminary Amendment. Claim 1 was also amended herein to remove the “optional” language in regard to the list of peaks. As such, Claim 1 now recites the list of peaks in combination, not in the alternative. Further, Claim 1 now recites the characterization parameters of Claims 2-4 to further define the recited crystal. Since the amended claims recite the same crystal disclosed and described in depth in the specification, the rejection under 35 U.S.C. § 112, 1<sup>st</sup>, should be withdrawn.

#### **Objections to the Specification and Claims**

The Office Action alleged that the Abstract recited a process, but did not set forth what the process involved. The Abstract has been amended herein to address the Examiner’s concerns.

Also, the typographical error regarding “amorphous” at page 1, line 20, has been corrected.

Lastly, the typographical error regarding “acetonitrile” in Claim 9 has been corrected.

**CONCLUSION**

Enclosed herewith is payment in the amount of \$1050.00 for the fee under 37 C.F.R. § 1.17(a)(3) for a Three-Month Extension of Time. No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees which may be required or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,  
NEEDLE & ROSENBERG, P.C.

/Christopher L. Curfman/

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**CERTIFICATE OF EFS-WEB TRANSMISSION UNDER 37 CFR § 1.8**

I hereby certify that this Response, including any items indicated as attached or enclosed, is being transmitted by EFS-WEB on the date indicated below.

/Christopher L. Curfman/

April 28, 2008

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Christopher L. Curfman

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Date